K110459

Surefire Medical requests that the attached "Summary" for the Surefire™ Infusion Catheter System be distributed upon request under the Freedom of Information Act. This report is a summary of the information presented in this 510(k) submission.

Owner/Manufacturer:	Surefire Medical, Inc. 8601 Turnpike Dr. Manufacturing Suite 206 Westminster, CO 80031	Surefire Medical, Inc. 12415 SW136Avenue Unit 3 Miami, FL 33186
Contact Person:	Cheryl Hastings VP Clinical and Regulatory Affairs 303.883.5554	
Date of Summary Preparation:	16 June 2011	
Trade Name:	Surefire™ Infusion Catheter System	
Common Name:	Intravascular Catheter	
Classification Name:	Intravascular Diagnostic Catheter	
Classification:	Class II	
Classification Regulation:	21 CRF Part 870.1200 - Diagnostic intravascular catheter.	
Product Code:	DQO	
Intended Use:	The Surefire™ Infusion Catheter System is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.	
Device Description:	The Surefire™ Infusion Catheter System is a two-part system comprised of an Infusion Microcatheter and a Guide Sheath.	
Principals of Operation/ Technology:	The Surefire™ Infusion Catheter System is operated manually.	

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Performance Testing & Verification Testing

- Kink Testing
- Tensile Testing
- High Pressure Injection Testing
- Hub Aspiration Testing
- Embolic Agent Infusion Compatibility Testing
- Package Integrity Testing
- Corrosion Testing
- Diagnostic Agent Compatibility Testing
- Trackability Testing
- Dimensional Inspection
- Coating Integrity
- Antegrade Flow Testing
- Infusion Efficiency
- Acute System Toxicity

Biocompatibility Testing

- **Pyrogenic**- Test is conducted based on USP, General Chapter, <151> Pyrogen Test. The procedure is recommended in ISO 10993-11
- **intra-cutaneous irritation** based on ISO 10993-10: **Toxicity** of the Paladin Catheter testing was based on International Organization for Standardization 10993-11
- **Hemolysis** was tested according to procedures based on ASTM F756, Standard Practices for Assessment of Hemolytic Properties of Materials and ISO 10993-4
- **Sensitization** was tested based on the requirements of ISO 10993-10
- **Particulate** – USP Standards
- **Cytotoxic effects** were tested following the guidelines of ISO 10993-5:
- **Complement System** was performed

Performance/Safety: A risk/hazard analysis was conducted according to EN ISO 14971 Medical Devices- Application of Risk management to medical devices. Performance characteristic for this indication for use were determined. It was then justified that the performance of the Surefire™ Infusion Catheter System is substantially equivalent to the performance and safety of the Terumo Radifocus Glidecath. A battery of tests were performed according to protocols based on the requirements of the following standards and was shown to meet the acceptance criteria that were determined to be applicable to the safety and efficacy of the device:

- ISO 10555-1 Sterile, single use intravascular catheters Part 1 General requirements.
- Surefire™ Infusion Catheter System Section 5-1 Premarket Notification Traditional 510(k) Submission 15 February 2011
- ISO 10555-2 Sterile, single use intravascular catheters Part 2 Angiographic catheters.
- ISO 10993-1 Biological Evaluation of medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile
- ISO 11135-1 Medical Devices –Validation and Routine Control of Ethylene Oxide Sterilization.

Additional Safety Information: Manufacturing controls include visual, functional, dimensional and sterility tests. Blood contacting materials were tested in accordance with the tests re commended in the FDA General program Memorandum. Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part -1 Evaluation and testing".

Discussion of Animal Data: The animal study data is submitted in this 510(k) and is on file at Surefire Medical.

Substantial Equivalence: The Surefire™ Infusion Catheter System is substantially equivalent in intended use, design, technology/principles of operation to the predicates. The Guide sheath is substantially equivalent to the Terumo Radifocus GLIDECATH, cleared under K090040. The Microcatheter is substantially equivalent to the EmboCath Plus Infusion Microcatheter by BioSphere Medical cleared under K062126. Differences between the devices do not raise any significant issues of safety or effectiveness.

Submitter Information:

Prepared by: Cheryl Hastings
VP Clinical and Regulatory Affairs

Prepared for: Surefire Medical, Inc.
8601 Turnpike Drive
Suite 206
Westminster, CO 80031

Date: June 16, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Surefire Medical, Inc.
c/o Ms. Cheryl Hastings
VP Clinical and Regulatory Affairs
8601 Turnpike Dr., Suite 206
Westminster, CO 80031

JUN 2 4 2011

Re: K110459
Trade/Device Name: Surefire™ Infusion Catheter System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQO
Dated: June 17, 2011
Received: June 20, 2011

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):	K110459
Device Name:	Surefire™ Infusion Catheter System
Indication for Use:	The SUREFIRE™ INFUSION CATHETER SYSTEM is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

Prescription Use ___X_____ AND/OR Over-The-counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH,

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110459

Indication for Use

510(k) Number (if known):	K110459
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(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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